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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, CAMTU TRAN	
ART UNIT	PAPER NUMBER
3772	
MAIL DATE	DELIVERY MODE
11/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/839,643	KEREN ET AL.	
	Examiner	Art Unit	
	Camtu T. Nguyen	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-51,59,60,62, 68-73,78,84,86-90,92 and 97-108* is/are pending in the application.

4a) Of the above claim(s) *62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-51,59,60,68-73,78,84,86-89,92 and 97-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 9/4/2009 has been entered.

Claims 49 and 84 have been amended.

Claims 52-58, 63-67, 74-77, 79-83, 85, 90-91, 93-96, and 109-112 have been cancelled.

Response to Arguments

Applicant's remarks directed to the King et al reference are persuasive, and thus, the rejection associated with the King et al reference has been withdrawn.

Applicant's remarks directed to the Bailey et al reference are acknowledged but deemed not persuasive with regards to point "(i)" presented on page 7-8. In particular, the Bailey et al's stent valve (40) opens to allow blood to flow therethrough upon pressure differential therebetween and closes by zero pressure differential therebetween, thus, disclosing the claimed devices. Furthermore, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re

Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Bailey et al reference is maintained at least to the device claims.

The Wolf & the Cosman references are maintained, at least for the reasons the Bailey et al reference is maintained.

The claims, as amended, have been carefully considered but deemed not allowable in view of the following rejection(s).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 49, 59, 84, and 103 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

When claim(s) recite(s) a device/apparatus with elements being "attached to" the human body, such recitation makes the claim(s) non-statutory.

In claim 49, the recitation **a shunt between a left atrium and a right atrium**.

In claim 59, the recitation **a shunt being positionable within a septum between a left atrium and a right atrium**.

In claim 84, the recitation **a valve in a heart septum two heart atria**.

In claim 103, the recitation **a shunt implantable in a septum between atria of the heart**.

These recitations positively set their devices on the human body.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, blood flow would not lead to the right ventricle when a valve implanted between two heart aria.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 49-51, 59-60, 71, 84, 86-89, 92, 97-102 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilk (U.S. Patent No. 7,294,115).

Wilk discloses in Figures 1-5 shunts with valves to be in the heart wall (HW) from ventricle (LV) into coronary artery (CA), however, Wilk discloses that these shuts with valves may also be applied to the right and left atria (column 11 lines 64-67).

Regarding claims 50 & 59 reciting fixation elements, Figure 5 illustrates flange (50) for purposes of attaching the shunts to septum between the atria.

Regarding claim 60, Figure 5 illustrates the shunt-implemented of Figure 4 with valve (50) permitting blood flow from the ventricle to the coronary artery (column 13 lines 61-65).

Regarding claim 70, Figure 3 illustrates the length of the shunt relative to the septum/heart wall (HW).

Regarding claim 71, Figures 8e & 8h illustrate the valve (808) is capable of continuous flow of small amount of blood.

Regarding claims 51, 84, 86-87, 98, 100, the Wilk's shunts with valves, when applied between the left atrium & right atrium, would perform the method of decrease/reduce blood pressure in a heart, specifically by flowing blood when there is pressure differential therebetween.

Regarding claim 88, under normal condition, pressure in the atrium is not more than 12 mm Hg when the mitral valve opens. With that in mind, when the Wilk et al shunts would, when positioned between the two heart atria, open when pressure is greater than normal condition of 12 mm Hg.

Regarding claim 89, should the Wilk's shunts origin in the left ventricle, the output would be in right ventricle.

Regarding claim 92, during Wilk's valve would open allowing blood passage during diastole in left–right ventricle arrangement.

Regarding claim 97, Figures 9 & 9b illustrates sensors (78, 78) for sensing the state of the heart and the valves of the shunts operate responding to the outputs of the sensors (76, 78) via receiver (84) and transmitter (82).

Regarding claim 99, the Wilk's valves would inherently close after drainage of blood reducing the mean pressure in the left atrium by 5 mm Hg.

Regarding claim 101, Figures 1a-1e illustrate the implantation of the shunt (22) using a catheter (12).

Regarding claim 102, implanting the Wilk's shunts between the left & right atria would indeed be in none other than a transseptal hole.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 59-60, 68-71, 73, and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Bailey et al (U.S. Patent No. 6,458,153).

Bailey et al discloses in a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising a valve (28) which opens allowing blood to flow through the

stent valve (40) upon a pressure differential therebetween and would close by zero pressure differential therebetween (column 11 lines 13-23).

Regarding claim 59 reciting the shunt device **positionable** within a septum between a left atrium & a right atrium, the Bailey et al's stent valve (40) is positioned through a septum mitral valve, hence, it is clearly capable of being positionable within a septum between a left atrium & a right atrium.

Regarding claims 60, 69, 71, and 73, the Bailey et al stent valve (40) comprising a valve (28) configured to allow passage of blood volume and is capable of gradual opening and/or closing.

Regarding claim 68, Figure 12a illustrates the stent valve (40) positioned in the mitral valve, a natural opening in the heart, which has an opening diameter of less than 5 mm.

Regarding claim 70, Figures 12a & 12b illustrates the stent valve (40) has a length not substantially greater than a thickness of the septum.

Regarding claim 78, Figure 2 in the Bailey et al reference illustrates fixation elements (22) attached to opposite sides of the stent valve (40).

Claims 72 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Patent No. 6,458,153) in view of Wolf et al (U.S. Patent No. 6,641,610).

Bailey et al discloses in Figures 7-11 a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising elements in these claims but does not teach a sensor and a controller as recited in claim 103.

Wolf et al discloses in Figure 7 shunt conduit (34) comprising a valve (32) operative in conjunction with a sensor (30) senses/detects the signal output produced from the heart muscle and an actuator (36) opens the valve (32) based on the reading of the sensor (30).

Therefore, it would have been obvious to one of ordinary skilled in the art to utilize the sensor (30) & the controller (36), taught by Wolf et al, with Bailey et al's stent valve (40) as such would regulate the stent valve (40) in order to prevent any potential back flow in the heart atria.

With regards to claims 72, Wolf et al discloses a hydrodynamic/electric pump (column 7 lines 4-7), for controlling the valve, of which is well known in the art to be outside of the patient's body.

Claims 104-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Patent No. 6,458,153)/Wolf et al (U.S. Patent No. 6,641,610), presented above, and further in view of Cosman (U.S. Patent No. 4,787,886).

Bailey et al/Wolf et al, presented above, discloses a stent valve (40) in the chamber-to-chamber (CC) configuration, the CC stent valve (40) comprising elements in these claims including a sensor and a controller but does not teach the sensor comprises a pressure.

Cosman discloses a shunt valve system comprising a pressure sensor. Therefore it would have been obvious to one skilled the art to use the sensor that senses/detects a pressure, taught by Cosman in place of Bailey et al's sensor for purposes of sensing/detecting a pressure in the patient's heart.

With regards to claims 106-108, the Bailey et al valve would open to relief pressure built in the atrium flow when pressure is above 20 mmHg, a pressure mark that is considered high for diastole cycle.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761